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EXAMINER				
ZHENG, LI				
ART UNIT		PAPER NUMBER		
1638				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/578,962

**Applicant(s)**

MARILLONNET ET AL.

**Examiner**

LI ZHENG

**Art Unit**

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 and 57 is/are pending in the application.
- 4a) Of the above claim(s) 1-35, 39-43, 46-55 and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-38, 44 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/5/2009; 5/10/2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1-55 and 57 are pending.

#### ***Election/Restrictions***

2. Applicant's election with traverse of Group XI, claims 44-45, in the reply filed on 4/30/2009 is acknowledged.

Applicants contend that Mallory et al. describes crossing of two plants, one being an amplicon transgenic line and one being a HC-Pro-expressing lines and that there is no indication that the sequence for replicon function of the amplicon expressing line of Mallory et al. have function-conservative differences from the sequence of the plant RNA virus from which the RNA replicon is derived (response, page 14, 2<sup>nd</sup> paragraph).

The office contends that given the undefined meaning of "function-conservative differences", this limitation was not given any weight when characterizing the technique feature linking different invention group.

The restrictions between Group VIII and Group XI are withdrawn due to the amendment to claim 44 which put claim 44 dependent on claim 36.

Applicants are advised that since the restrictions between Groups VIII and XI are withdrawn, if any claim(s) that include(s) the limitation of the examined claims is/are presented in a continuation or divisional application, the claim of the application may be subject to a provisional statutory and/or nonstatutory double patenting rejection over

the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 no longer apply. MPEP804.01.

Claims 1-35, 39-43, 46-55 and 57 are withdrawn for being drawn to non-elected inventions.

Claims 36-38 and 44-45 are examined on the merits.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.0. See, for example, pages 21, 33 and 38.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 36-38 and 44-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 36, the recitation "function-conservative differences" renders the claim indefinite. It is unclear what is considered to be "function-conservative differences". The metes and bounds are not clear.

In claim 44, the recitation "capable of forming nuclear introns near or within A/U-rich localities of said sequences for replicon function" render the claim indefinite. First it is unclear what is considered to be "capable of ". Second, it is unclear what is considered to be "near". Third, it is unclear what is considered to be A/U rich. What is the cut-off for being considered as A/U rich. The metes and bounds are not clear.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Klimyuk et al. (U.S. Patent Pub. No. 2004/0255347).

The claims are drawn to a process of transiently expressing a sequence of interest in a plant, plant part, or plant cell culture, comprising: transforming a plant, plant part, or plant cell culture with a heterologous DNA having a sequence encoding an RNA replicon operably linked or linkable to a transcription promoter, wherein said sequence encoding an RNA replicon contains (i) sequences for replicon function of said RNA replicon, said sequences being derived from a sequence of a plant RNA virus, (ii) a sequence of interest, whereby said sequences for replicon function exhibit at selected localities of said sequences of said plant RNA virus function-conservative differences from said sequence of said plant RNA virus, said differences causing an increased frequency of replicon formation compared to an RNA replicon not exhibiting said differences; or wherein said transforming is performed by *Agrobacterium*-mediated transient transformation of T-DNA; or wherein said transforming is performed by agroinfiltrating the stem or leaves of tobacco plant.

Klimyuk et al. teach a process for expressing of one gene of interest from viral vector assembled from two CrTMV based provectors through site specific recombination (paragraph [0176] and claim 1). Klimyuk et al. teach that delivery of viral vector constructs by infiltration of *agrobacterium tumefaciens* suspension into Plant leaves of tobacco. Klimyuk et al. also teach the process is done by transient expressing (paragraph [0007] and claim 19). Klimyuk et al. also teach the invention allows for

higher efficiency of gene expression compared to conventional system by reducing the size (paragraph [0110]). Given that the recitation "function-conservative differences" is indefinite and interpreted as any difference that cause increase viral replicon formation. The reference teaches all the limitation set forth the instant claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 36-38 and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klimyuk et al. (U.S. Patent Pub. No. 2004/0255347) in view of Rose (2002, RNA 8:1444-1453).

Claims of 36-38 are described above.

Claim 44 further contains the limitation that one or more intron is inserted near or within A/U-rich localities of said sequence for replicon function.

The Office interprets the recitation "near A/U localities of said sequence for replicon function" to be anywhere due to the lack of definition for the recitations "near" and "A/U rich localities".

The teaching of Klimyuk et al. is discussed as above.

Klimyuk et al. do not teach the limitation that one or more intron is inserted near or within A/U-rich localities of said sequence for replicon function.

Rose teaches that insertion of heterologous intron enhance expression of gene (abstract).

Given the recognition of those of ordinary skill in the art of the value of expressing gene of interest as taught by Klimyuk et al. , it would have been obvious for a person with ordinary skill in the art to generate an expression vector of Klimyuk et al. by inserting the intron of Rose into 5' region of the gene of interest, resulting in the instant invention. One skilled in the art would have been motivated to do so given the teaching of Rose that insertion of a plant intron would enhance the expression of gene of interest. .

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031.



The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Li Zheng/

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